JUL 3 1 2012

510(k) Summary
Astra Tech AB
OsseoSpeed™ Plus
K120414

July 23, 2012

ADMINISTRATIVE INFORMATION

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Head of Regulatory Affairs

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San Diego, CA 92130
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: OsseoSpeed™ Plus
Common Name: Dental implant and abutment
Classification Name: Implant, endosseous, root form
Endosseous dental implant abutment

Classification Regulation: Class II, 21 CFR 872.3640
Product Code: DZE, NHA

Classification Panel: Dental Products Panel
Reviewing Branch: Dental Devices Branch

INTENDED USE

Implants:
The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:

- replacing single and multiple missing teeth in the mandible and maxilla,
- immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge,
- especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective,
- immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.

The intended use for OsseoSpeed™ Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisors.

Abutments:
Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.

Atlantis Abutments:
The Atlantis™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.

DEVICE DESCRIPTION

The purpose of this submission is to expand the OsseoSpeed™ Plus Implant System to include all the components of the previously cleared OsseoSpeed System. The OsseoSpeed Plus Implant System, cleared September 26, 2011 under K111287, has the same design as the OsseoSpeed system, except for addition of an anti-rotation feature to the implant/abutment interface.

The OsseoSpeed Plus System includes implants with diameters ranging from Ø3.0 mm to Ø5.4 mm and lengths ranging from 6 mm to 17 mm. Radiographic guides are available for all implant sizes. Abutments sizes range from Ø3.0 mm to Ø5.4 mm in straight and angled designs

ranging from 15° to 30°. Abutment designs include coverscrews, healing abutments, temporary abutments, cast-to abutments, ball abutments, straight and angled abutments.

EQUIVALENCE TO MARKETED DEVICE

Astra Tech OsseoSpeed™ Plus Implant System is substantially equivalent in indications for use and design principles to the following legally marketed predicate devices:

Implants:	K111287, K101732, K091239, K080396.
Abutments:	K120338, K112138, K111390, K110356, K101849, K101005, K083805, K083496, K081666, K072624, K063286, K980698, K974738, K931767.

The subject device and the predicate devices have the same intended use and have the same technological characteristics and are made of the same materials. They encompass the same range of physical dimensions, including diameter and length of the implants, and diameter, height and angle of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods.

Non-clinical testing data provided or referenced to demonstrate substantial equivalence included detailed engineering analysis, dimensional analysis, surface area and bone-to-implant contact area analysis, and static and dynamic compression-bending testing according to ISO 14801.

Any differences in the technological characteristics between the subject device and the predicate devices do not raise new issues of safety or efficacy.

The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, OsseoSpeed Plus has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Astra Tech AB
C/O Ms. Linda K. Schulz
Senior Regulatory Affairs Specialist
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

JUL 31 2012

Re: K120414
Trade/Device Name: OsseoSpeed™ Plus
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 23, 2012
Received: July 24, 2012

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120414

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120414